Original Article

Continuous Deep Sedation at the End of Life of Children in Flanders, Belgium

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Abstract

Context. Few guidelines have yet been put forth for continuous deep sedation in pediatrics, and empirical data on the use of this practice in minors are rare.

Objectives. To estimate the incidence of continuous deep sedation in minor patients (aged 1–17) and describe the characteristics of, and the decision-making process before, continuous deep sedation.

Methods. An anonymous population-based postmortem survey was mailed to all physicians signing the death certificates of all patients aged 1–17 years who died between June 2007 and November 2008 in Flanders, Belgium. The questionnaire concerned whether or not continuous deep sedation was used at the end of life and measured characteristics of sedation and the decision-making process preceding it.

Results. Response rate was 70.5% ($n = 165$). Of all children, 21.8% had been continuously and deeply sedated at the end of life. Duration of sedation was one week or less in 72.4% of cases, and artificial nutrition and hydration were administered until death in 54.3% of cases. Benzodiazepines were used as the sole drug for sedation in 19.4% of cases, benzodiazepines combined with morphine in 50%, and morphine as the sole drug in 25%. In 23.5% of cases, physicians had the explicit intention, or the concurrent intention, to hasten death. Only 3.0% of patients requested sedation and 6.1% consented. Parents consented in 77.8% of cases and requested sedation in 16.7%.

Conclusion. Minor patients were commonly kept in continuous deep sedation or coma until death in Flanders, Belgium. Given the high incidence of the practice and indications that it is often used without involving the patient—and sometimes with a life-shortening intention—the development of specific guidelines for sedation in children might contribute to due care practice. J Pain Symptom Manage 2011;41:449–455.

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Key Words
Deep sedation, intractable pain, palliative care, decision making

Introduction

Continuous deep sedation is an acceptable last resort option to alleviate refractory symptoms in terminally ill patients.[1] Nationwide studies in European countries show that the practice precedes between 2.5% and 16.5% of all adult deaths and that it has become more widespread in recent years.[2–6] Single-center studies exist that suggest that sedation is frequently used in pediatric end-of-life practice,[7–9] although this has not been confirmed at a population level.

Continuous deep sedation at the end of life poses clinical and ethical challenges to practitioners.[10] To help them deal with these challenges, several guidelines and recommendations have been put forward,[11–16] including indications for palliative sedation, whether or not artificial food and fluids should be administered, and whether life shortening should be intended. Although some people argue that continuous deep sedation can have a life-shortening effect, this is still debated. This is one reason why its practice should respect strict due care requirements.[17–20] In minor patients, decision making is further complicated by a limited capacity to make autonomous decisions because of still-developing mental competency, by legal restraints on decision making by minors, and by the involvement of parents as a third party in the process.

Given these important clinical and ethical challenges, it is striking that few guidelines have yet been put forward for pediatric practice and that empirical data on the practice of continuous deep sedation in minors are rare.[21,22] This study aimed to estimate the incidence of continuous deep sedation in minor patients (aged 1–17 years) in Flanders, Belgium and describe the characteristics of, and the decision-making process leading up to, its practice.

Methods

During an 18-month period from June 2007 until November 2008, an anonymous self-administered questionnaire was mailed by the Flemish Ministry of Health to all physicians who signed the death certificates of all 250 patients, ages 1–17 years, residing in Belgium who died in Flanders within that period. To enhance response, the Total Design Method was followed, with a maximum of three reminders per case.[23] A complex mailing procedure, with a lawyer as intermediary between physicians and the Flemish Ministry of Health, was used to ensure anonymity of both physician and patient.[24] A one-page nonresponse survey was mailed to physicians who did not respond after three reminders.

The questionnaire was similar to those used in previous studies in adults and neonates,[2,4,25,26] albeit slightly adapted to fit pediatric practice by including questions on the involvement of parents and minor patients. When death had not been sudden and unexpected according to the physician, he or she was asked, "Was the patient continuously kept in deep sedation or coma until death, by means of one or more drugs?" This implies that, regardless of whether sedation was initiated by the physician or a consequence of disease progression, only patients who were kept in a coma by means of drugs could be considered continuously and deeply sedated until death. Further questions were aimed at eliciting the characteristics of continuous deep sedation: administration of artificial food/fluids until death, drugs used, duration of sedation, consent or request by parents and/or patient, alternatives to sedation, and the physician's life-shortening intention when engaging in sedation. The Flemish Ministry of Health provided clinical and demographic information as recorded on the death certificate (age, gender, cause, and place of death), which the lawyer linked case by case to data from the questionnaires. Afterward, the data were made anonymous. Standard descriptive statistics were used to analyze the data. Chi-squared statistics were used to investigate differences between cases where continuous deep sedation was used and other nonsudden deaths where no continuous deep sedation was used. SPSS 15.0 (SPSS Inc., Chicago, IL) was

used for all analyses. Level of significance was set at $P < 0.05$.

The study was approved by the Ethical Review Board of the University Hospital of the Vrije Universiteit Brussel and the Ethics Committee of Ghent University Hospital, and positive recommendations were received from the Belgian National Disciplinary Board of Physicians and the Belgian Federal Privacy Commission.

Results

In 16 of the 250 cases, the physician received the questionnaire but was unable to provide information, according to an additional nonresponse survey, because of lack of access to the patient's medical file or patient identification. For 165 of the 234 remaining cases, a completed questionnaire was returned (response rate 70.5%). For 88 of 165 cases, the physician estimated that death had been sudden and unexpected.

Of all patients, 36 had been continuously and deeply sedated at the end of life. This was 21.8% of all studied deaths and 46.8% of nonsudden deaths. Patient characteristics are presented in Table 1. Benzodiazepines were used as the sole drug for sedation in seven patients (19.4%), benzodiazepines combined with morphine in 18 patients (50.0%), and morphine as the sole drug in nine patients (25.0%) (Table 2). One patient had been sedated for more than two weeks, whereas most were sedated for one week or less (72.4%). Artificial nutrition and hydration were administered until death in more than half of the cases (54.3%) and were withdrawn during sedation in eight cases (22.9%). The proportion of patients receiving artificial nutrition or hydration during sedation differed according to place of death: 44.4% of patients receiving continuous deep sedation at home received artificial nutrition and hydration at some point during sedation, compared with 91.3% of the patients in hospital (data not shown in the table).

Physicians indicated having had the explicit intention, or the concurrent intention, of hastening death in eight cases (25.05%). When artificial food and fluids were administered until death, 17.6% of physicians reported an explicit or concurrent intention of hastening death, whereas 37.5% and 33.3% did so when artificial food and fluids were withdrawn during sedation or withheld. In 27 cases (84.4%), physicians indicated that there was no alternative to continuous deep sedation for treating the patient's symptoms (Table 2).

The decision to use continuous and deep sedation was made without patient involvement in most cases: one patient requested sedation (3.0%) and two patients consented (6.1%) (Table 2). No patient dying at age 11 or younger consented with or requested to be sedated. In 70% of patients dying at age 12 and older, there was no request for or consent with sedation (data not shown in the table). Parents consented in most cases (77.8%) and requested sedation in six cases (16.7%). In six cases (16.7%), there was no request or consent from the parents.

Discussion

Minor patients were commonly kept in continuous deep sedation or coma until death (21.8% of all deaths and 46.8% of nonsudden deaths) in Flanders, Belgium. Most sedation started one week or less before death, and artificial nutrition and hydration were administered until death in more than half of the cases. Physicians had the explicit or concurrent intention of hastening death in a quarter of cases. Parents consented to sedation in most cases, whereas the patients were seldom involved in decision making.

The present study is, to our knowledge, the first to investigate the practice of continuous deep sedation in minors across different patient groups and care settings. A good response rate was attained. The method used has been successfully applied in previous studies and allows the making of reliable estimates of end-of-life practices.[2,4,25] However, only the physician's perspective was studied; the perspective of parents was not included. The present study was retrospective and descriptive, thus less suitable for providing in-depth explanations of its findings.

The incidence of continuous deep sedation in our study in minor patients was higher than the incidences found in recent population-wide studies in adult patients in Belgium (14.5%).[5,6] The high incidence may partly be related to a lack of appropriate

Table 1
Demographic Characteristics, Cause of Death, and Treatment Duration for Pediatric Patients Receiving Continuous Deep Sedation at the End of Life ($n = 36$) vs. Those Who Were Not ($n = 41$)

		Nonsudden Deaths[a]		Sudden Deaths[a,b]
		CDS	No CDS	
		n (%)	*n* (%)	*n* (%)
Number of deaths		36	41	88
% of all deaths		21.8	24.8	53.3
Gender				
Male		22 (61.1)	22 (53.7)	48 (54.5)
Female		14 (38.9)	19 (46.3)	40 (45.5)
	P-value[c]	0.510		
Age				
1–5		18 (50.0)	17 (41.5)	27 (30.7)
6–11		8 (22.2)	11 (26.8)	13 (14.8)
12–17		10 (27.8)	13 (31.7)	48 (54.5)
	P-value[c]	0.752		
Cause of death				
External (including accidents, traffic accidents, and suicide)		7 (19.4)	7 (17.1)	60 (68.2)
Cancer		11 (30.6)	11 (26.8)	3 (3.4)
Central nervous system		4 (11.4)	6 (14.6)	6 (6.8)
Congenital		3 (8.3)	6 (14.6)	5 (5.7)
Cardiovascular		2 (5.6)	0 (0.0)	6 (5.7)
Other		9 (25.0)	11 (26.8)	9 (8.0)
	P-value[c]	0.655		
Place of death				
Home		10 (27.8)	15 (36.6)	28 (31.8)
Hospital		23 (63.9)	18 (43.9)	25 (28.4)
Other (including the road and institutions)		3 (8.3)	8 (19.5)	35 (39.8)
	P-value[c]	0.168		
Time in treatment				
1–7 days		9 (25.0)	9 (22.5)	
1 week–6 months		12 (33.3)	3 (7.5)	
>6 months		15 (41.7)	28 (70.0)	
	P-value[c]	0.010		

Number of observed cases (percentage). Percentages do not always add up to 100 because of rounding.
CDS = continuous deep sedation.
[a]Cases were categorized as sudden when the physician indicated that death had been sudden and completely unexpected and when the physician indicated that the first contact with the patient was after the child's death.
[b]Information on time in treatment was not available for sudden deaths.
[c]*P*-value for Chi-squared statistic testing differences in the distribution of described characteristics between cases of CDS and nonsudden deaths without CDS.

optimal pain control in children because of the barriers to using sufficiently high doses of drugs and to the limited capacity of young children to express their symptom burden verbally.[27] Despite recent advances in pediatric pain relief, providing optimal symptom relief remains challenging for caregivers. To make sure that total symptom control is attained, physicians caring for minor patients may, therefore, be more readily inclined to resort to sedation. In most cases, physicians indicated that sedation was used where there were no options left to alleviate symptoms and only when death was imminent. Further studies on optimal dosages of pain medication for pediatric use, and improved training in palliative care and aggressive symptom control, may help physicians to resort to sedation less readily.

At least four different types of sedation may occur at the end of life. The total proportion of 22% observed in our study is thus a combination of different practices. A first type is "palliative" or "terminal" sedation, which is used as a last resort option to treat refractory symptoms in imminently dying patients. This type of sedation has been investigated frequently for the population of adult patients, and guidelines for good clinical practice have been formulated.[11–16] A second type of sedation is used to calm patients to facilitate

Table 2
Characteristics of CDS and the Decision-Making Process

	n	%
Total	36	100
Drugs used		
Only benzodiazepines	7	19.4
Benzodiazepines and morphine	13	36.1
Benzodiazepines, morphine, and other	5	13.9
Only morphine	9	25.0
Morphine and other drug	2	5.6
Duration of sedation[a]		
0–48 hours	12	41.4
2–7 days	9	31.0
1–2 weeks	7	24.1
>2 weeks	1	3.4
Artificial nutrition and hydration[a]		
Administered until death	19	54.3
Withdrawn during sedation	8	22.9
Withheld	8	22.9
Intention of hastening death[a]		
No intention	9	28.1
Taking into account possible hastening of death	15	46.9
Co-intention	4	12.5
Explicit intention	4	12.5
Alternatives to CDS[a]		
None	27	84.4
Only ending the patient's life	3	9.4
Unspecified other alternatives	2	6.3
Main goal of care in the last week before death		
Cure	14	38.9
Prolongation of life	3	8.3
Comfort	19	52.8
Patient request for or consent to CDS[a,b]		
Request	1	3.0
Consent	2	6.1
No[c]	30	90.9
Parental request for or consent to CDS[b]		
Request	6	16.7
Consent	28	77.8
No[c]	6	16.7

Number of observed cases and percentages. Percentages do not always add up to 100 because of rounding.
CDS = continuous deep sedation.
[a]Data were missing for seven cases (duration of sedation), four cases (alternatives), three cases (patient request/consent), two cases (physician's intention), and one case (artificial food or fluids).
[b]Multiple answers were possible, total percentage may add up to more than 100.
[c]No information was available on whether consent was solicited by the physician or not.

certain treatments, such as ventilation after surgery. However, the patient's condition may worsen while under sedation, and it may consequently become irreversible and impossible to bring the patient back to consciousness. This second type of sedation is used when the main goal of treatment is curative, and the intention of professional caregivers is still to preserve the patient's life. Our finding that artificial food and fluids were administered until death in just more than half of the cases of sedation may indicate that this type of sedation occurred in our study. A third type of sedation is an unintended consequence of a gradual increase in pain medication. In our study, a quarter of physicians reported that they had only used morphine to sedate the patient. Finally, sedation also may sometimes be used as a covert form of life ending, which was reported as their intention or co-intention by a quarter of physicians. The types of sedation described above would all be interpreted as continuous deep sedation until death by the physician, but the conditions under which sedation was started may have been entirely different. Unfortunately, the study design did not allow for clearly distinguishing between different types of sedation. Further prospective studies may help to clarify this issue.

According to Article 12(2) of the Belgian Law on the Rights of the Patient (2002), which implicitly applies to continuous deep sedation, minor patients who are thought to be capable of judging their own interests may exercise their medical rights autonomously. In the great majority of cases studied here, the decision to sedate was taken with parental consent, but strikingly, patients themselves were seldom involved in the decision making, if they died at age 12 or older. Of course, discussion would have been impossible in cases where sedation was an unintended side effect of pain and symptom control. The findings may indicate that physicians make these decisions in the patient's stead, in consultation with parents, in their best interests, sometimes because patients are judged to be too young and sometimes possibly because of their diminished consciousness at the time of the decision. However, such circumstances cannot always justify the exclusion of minors from the decision-making process. If possible, some kind of discussion should perhaps be initiated early enough in the disease process. Moreover, in cases where there was neither parental request nor consent, it is possible that patients and parents missed farewell opportunities. As the present data were limited in providing a full explanation of the finding, further studies are needed to clarify whether the

decision-making process preceding sedation in minors is indeed less than optimal, and if so, whether this affects bereavement outcomes.

However, contrary to existing guidelines, physicians intended, or had a concurrent intention, to shorten life in a quarter of cases of continuous deep sedation in the present study. Almost half of physicians reported that they had taken possible hastening of death into account when engaging in sedation. These physicians may have observed the principle of double effect in these cases: they accept that sedation has two effects (symptom relief and shorter longevity), they only intend the good effect and accept the negative effect as a necessary but unintended side effect. However, our results do not preclude the use of sedation where euthanasia might otherwise have been chosen if it were legal in minors. Further studies in other populations are needed to establish whether this finding can be generalized to other countries, where the legal framework surrounding euthanasia is different from Belgium, and physicians hold less permissive attitudes toward the practice.

Conclusion

The present study indicates that minor patients were commonly kept in continuous deep sedation or coma until death in Flanders, Belgium. Given the high incidence of the practice, and indications that it is sometimes used with a life-shortening intention without involving the patient, the development of specific guidelines for sedation in children appears to be appropriate to guide physicians and guarantee the practice of due care. These guidelines should be formulated with adequate attention to ethical and legal decision making. Further in-depth research is warranted to improve understanding of how decisions are made, why minor patients are seldom involved in them, and how sedation relates to acts with an explicit life-shortening intention.

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